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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert Savit

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

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DELIVERY MODE

04/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,781	Applicant(s) SAVIT ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claim 1 is objected to because of the following informalities:

Lines 2 and 4 call for first and second data sensors “positioned on the scalp of a/said subject”. The human body may not be claimed. For the purposes of examination, the phrases will be treated as though reading “configured to be positioned on the scalp of a/said subject”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose at any point performing measurements at time points having any interval between measurements; the claims have introduced new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 11, the processor is used to find first and second predictability values, but line 13 refers to "said first/second marginal predictability value". The inconsistency between the two makes the claim indefinite. For the purposes of examination, the claim will be treated as though both instances involve a plurality of values.

7. Claims 4 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claim what is separated by ten minute intervals.

Claim Rejections - 35 USC § 103

8. Claims 1-3, 5-14, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over 3,696,808 to Roy et al (Hereinafter "Roy") in view of 5,995,868 to Dorfmeister et al (Hereinafter "Dorfmeister").

Regarding claims 1, 5, 12, and 16, Roy discloses a system and method which is used for brain wave analysis (Abstract of Roy). A first data sensor (31,48 of Roy) is positioned on the scalp of a subject near the focal point of ictal onset and a second data

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sensor (32, 49 of Roy) positioned on the scalp of the subject, where the second data sensor is remote from the first data sensor (Fig. 3 and Col. 6, lines 7-17 of Roy). The signals collected from different sides of the brain are filtered and cross correlated in order to determine a correlation coefficient that is indicative of the epileptic seizure (Col. 5, lines 20-68 of Roy). The signals' amplitude and phase differences is calculated after the collected signals are passed through a comparator and the ictal onset is predicted by difference in the first marginal predictability value and a second marginal predictability value (102, 103 and Col. 3, lines 40-68 and Col. 5, lines 20-68 of Roy). Roy also teaches that the correlation coefficient is calculated using a non-linear algorithm (Col. 5, lines 25-35 of Roy); correlation is a measure of the similarities of the signals, another way of phrasing finding decreasing differences. Roy collects data at a plurality of time points (figure 13).

However, Roy fails to teach that a processor analyzes the collected data to provide a nonlinear mathematical manipulation of the collected data.

Dorfmeister teaches a system (10 of Dorfmeister) and method used for analyzing signals representative of a subject's brain activity in a signal processor (12 of Dorfmeister) for information indicating the subject's current activity state and for predicting a change in the activity state. Dorfmeister teaches that a combination of nonlinear filtering methods is used to perform real-time analysis of the electro-encephalogram (EEG) or electro-corticogram (ECoG) signals from a subject patient for information indicative of or predictive of a seizure, and to complete the needed analysis at least before clinical seizure onset. The system then performs an output task for

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prevention or abatement of the seizure, or for recording pertinent data (Abstract of Dorfmeister). The filters are used to differentiate between the ictal and non ictal components of each input signal (Col. 10, lines 16-30 of Dorfmeister).

Therefore it would have been obvious to one having ordinary skill in the art to use a nonlinear filter in a processor similar to the one taught by Dorfmeister in the brain wave monitoring device and method of Roy to manipulate the input signals in order to distinguish between ictal and non ictal components of the input signals to reduce the processing time and increase the accuracy of the seizure prediction (Col. 4, lines 43-68 of Dorfmeister).

In reference to claims 2 and 13, the first and second data sensors comprise electrodes (Fig. 4, helmet 30, probes 31 and 32 of Roy).

In reference to claims 3 and 14, the electrodes record electroencephalogram data from the subject (Col. 1, lines 52-64 of Roy).

In reference to claims 6, 8 and 17, 19, the system and method further comprise a subject warning device configured to receive information from the processor (Col. 9, lines 10-26 and audio or LED or any out put for of warning 34 of Dorfmeister).

In reference to claims 7 and 18, the information comprises information predictive of an ictal onset (Figs. 8 and 11 of Roy and Col. 9, lines 10-26 of Dorfmeister).

In reference to claim 9, the processor further comprises a computer readable memory (105, 207 and 208 of Roy and 36 of Dorfmeister).

In reference to claims 10 and 20, the system and method further comprise an anti-seizure agent (pump and injector 32 and stimulator 28 of Dorfmeister) administering device in communication with the processor, where the anti-seizure agent administering device administers an anti-seizure agent to the subject (Col. 9, lines 10-26 of Dorfmeister).

In reference to claims 11 and 21, the anti-seizure agent administering device is selected from the group consisting of micro pumps and electrical stimuli devices (pump and injector 32 and stimulator 28 of Dorfmeister).

9. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roy in view of Dorfmeister, as applied above, and further in view of Boling (US 2003/0195602).

Roy in view of Dorfmeister discloses all the elements of the claimed inventions, as described above, except for the plurality of time points being separated by ten minute intervals. Boling teaches measuring biosignals to predict an ictal onset in a subject where the measurements are taken at time points separated by non-recording intervals (paragraphs [0203], [0207]), in order to reduce the amount of data captured by the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have configured the system of Roy in view of Dorfmeister to capture data at time points separated by non-recording intervals, as taught by Boling, in order to reduce the data captured by the system. The Examiner notes that Roy in view

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of Dorfmeister and Boling does not expressly disclose the interval between measurements being ten minutes; at the time the invention was made, it would have been an obvious matter of design choice for a person of ordinary skill in the art to separate measurements by ten minutes because the Applicant has not disclosed that the exact interval between measurements provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that the interval of Boling, or Applicant's interval, would perform equally well to minimize measurements. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Roy in view of Dorfmeister and Boling to take measurements at ten minute intervals, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Roy in view of Dorfmeister and Boling.

Response to Arguments

10. Applicant's arguments filed 14 October 2008 have been fully considered but they are not persuasive.

Applicant has argued that Roy in view of Dorfmeister does not teach finding decreasing differences between predictability values measured over multiple time points. The examiner disagrees. As correlation increases, differences decrease. Further, Roy performs a continuous measurement, which inherently includes a plurality of time points.

The rejections stand as FINAL.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6484132 to Hively, which discloses similar inventions.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735